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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,982	10/27/2000	F. Richard Bringhurst	0609.4430001/JAG/CMB	1728

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	8

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/696,982	Applicant(s) Bringhurst et al.	
Examiner John Ulm	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 18, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4) Claim(s) 2 and 6-8 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2 and 6-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

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- 1) Claims 2 and 6 to 8 are pending in the instant application. Claim 2 has been amended as requested by Applicant in Paper Number 6, filed 18 April of 2002.
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claims 2 and 6 to 8 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,183,974 because the claimed subject matter in the patent is encompassed in its entirety by the instant claims. Applicant's arguments in traversal of this rejection are not persuasive because a generic claim is always obvious over a species claim encompassed by that generic claim. Applicant has failed to identify that limitation in the instant claims which is not met by the patent claim. These claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Further, with respect to the newly added limitations to claim 2, the subject matter now claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application

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which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

See also MPEP § 804.

5) Claims 2 and 6 to 8 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements for those reasons of record in section 4 of Paper Number 4. Applicant's traversal of this rejection completely fails to explain how one can distinguish between a compound which effects either of the two measured pathways directly or through a mechanism other than a heterologous receptor and a compound which effects either of these pathways indirectly by activating or inhibiting the heterologous receptor of interest. Clearly some comparative step between a cell comprising the recombinant receptor and a cell lacking that receptor would be a minimal requirement for the claimed method to meets its functional requirements.

6) Claims 2 and 6 to 8 stand rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Because the claimed invention is incomplete for those reasons given under 35 U.S.C. 112, second paragraph, above, it is inoperative.

7) Claims 2 and 6 to 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Catanzariti et al. publication (BioTechniques 15(3):474-479, Sep. 1993) in view of the combination of the Segre et al. patent (5,494,806) and the Bringhurst et al. publication (Endocrinology 132(5):2090-2098, May 1993) for those reasons of record in section 6 of Paper Number 4. Applicant has essentially traversed this rejection on the basis that Applicant has discovered unexpected properties which could not have been predicted from the prior art. These

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discoveries are not disputed. However, the properties identified by Applicant were entirely inherent to that assay system which was described in the Bringhurst et al. publication more than a year before the instant application was filed. *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied , 500 U.S. 904 (1991), held that "[p]rima facie case of obviousness of chemical composition is established if there is structural similarity between claimed and prior art subject matter, provided by combination of references or otherwise, and if prior art gives reason or motivation to make claimed composition". This decision further held that the "discovery that claimed composition possesses property not disclosed for prior art does not alone defeat prima facie case". In the instant case the claimed method and the prior art method both comprise those same unexpected properties identified by Applicant. Further, there was ample express motivation in the prior art relied upon, in the complete ignorance of these unexpected properties, to produce the now claimed invention. "The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972)", "*In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991)". "Although *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be

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motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention" (M.P.E.P. 2144).

8) Applicant's arguments filed 18 April of 2002 have been fully considered but they are not persuasive for those reasons given above.

9) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196



JOHN ULM
PRIMARY EXAMINER
GROUP 1800